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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/499,662	02/09/00	SERIZAWA	N 980126CIP/HG

HM12/0702
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EXAMINER	
UNGAR,S	
ART UNIT	**PAPER NUMBER**
1642	8

DATE MAILED: 07/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/499,662	Serizawa et al
Examiner	**Art Unit**
Ungar	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 9, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-119* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-119* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

1. Claims 1-119 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 1-6, 10-11, 16-19, 22-29, 41-55 are drawn to are drawn to an antigen binding region specific for an epitope of the Fas antigen, said epitope being conserved between a primate and a non-primate animal, monoclonal antibody and hybridoma cell line in Class 530, subclass 387.1.

Group 2. Claim 7-9, 12-13, 16-19, 26-29, 41-55, 58-60 are drawn to an antibody produced by the hybridoma HFE7A, classified in Class 530, subclass 387.3.

Group 3. Claims 14-15, 16-18, are drawn to recombinant antibody, classified in Class 530, subclass 387.1.

Group 4. Claim 21 is drawn method of evaluating therapies classified in Class 424, subclass 130.1.

Group 5. Claim 30 is drawn to a DNA encoding a single polypeptide portion of a molecule of any of claims 1, 6, 8, 9.

Group 6. Claim 31 are drawn to a DNA comprising residues 100-753 of SEQ ID NO:49, classified in Class 536, subclass 23.1. Claim 30 will be examined if it is drawn to the elected Group.

Group 7. Claim 31 are drawn to a DNA comprising residues 100-753 of SEQ ID NO:49, classified in Class 536, subclass 23.1. Claim 30 will be examined if it is drawn to the elected Group.

Group 8. Claim 31 are drawn to a DNA comprising residues 100-753 of SEQ ID NO:51, classified in Class 536, subclass 23.1. Claim 30 will be examined if it is drawn to the elected Group.

Group 9. Claim 31 are drawn to a DNA comprising residues 100 to 753 of SEQ ID NO:53, classified in Class 536, subclass 23.1. Claim 30 will be examined if it is drawn to the elected Group.

Group 10. Claim 31 are drawn to a DNA comprising residues 100-753 of SEQ ID NO:106, classified in Class 536, subclass 23.1. Claim 30 will be examined if it is drawn to the elected Group.

Group 11. Claim 31 are drawn to a DNA comprising residues 100-753 of SEQ ID NO:108, classified in Class 536, subclass 23.1. Claim 30 will be examined if it is drawn to the elected Group. Claim 30 will be examined if it is drawn to the elected Group.

Group 12. Claim 32 is drawn to a DNA comprising residues 82-3042 of SEQ ID NO:88, classified in Class 536, subclass 23.1.

Group 13. Claim 32 are drawn to a DNA comprising residues 84-2024 of SEQ ID NO:116, classified in Class 536, subclass 23.1.

Group 14. Claims 33, 35 are drawn to a DNA and host cell comprising residues 1-218 of SEQ ID NO:50, classified in Class 536, subclass 23.1. Claims 37-38 and 40 will be examined as they are drawn to the elected Group.

Group 15. Claims 33, 35 are drawn to a DNA and host cell encoding residues 1-218 of SEQ ID NO:50, classified in Class 536, subclass 23.1. Claims 37-38 and 40 will be examined as they are drawn to the elected Group.

Group 16. Claims 33, 35 are drawn to a DNA and host cell encoding residues 1-218 of SEQ ID NO:52, classified in Class 536, subclass 23.1. Claims 37-38 and 40 will be examined as they are drawn to the elected Group.

Group 17. Claims 33, 35 are drawn to a DNA and host cell encoding residues 1-218 of SEQ ID NO:54, classified in Class 536, subclass 23.1. Claims 37-38 and 40 will be examined as they are drawn to the elected Group.

Group 18. Claim 33, 35 are drawn to a DNA and host cell encoding residues 1-218 of SEQ ID NO:107, classified in Class 536, subclass 23.1. Claims 37-38 and 40 will be examined as they are drawn to the elected Group.

Group 19. Claim 33, 35 are drawn to a DNA and host cell encoding residues 1-218 of SEQ ID NO:109, classified in Class 536, subclass 23.1.

Claims 37-38 and 40 will be examined as they are drawn to the elected Group.

Group 20. Claims 34, 36 are drawn to a DNA and host cell encoding residues 1-451 of SEQ ID NO:89, classified in Class 536, subclass 23.1. Claims 37-38 and 40 will be examined as they are drawn to the elected Group.

Group 21. Claim 34, 36 are drawn to a DNA and host cell encoding residues 1-451 of SEQ ID NO:117, classified in Class 536, subclass 23.1. Claims 37-38 and 40 will be examined as they are drawn to the elected Group.

Groups 22-29 Claim 39 is drawn to E. Coli eight different cell lines, each of which is a separate invention. Applicant is required to elect a single cell line for examination.

Group 30. Claim 34, 36 are drawn to a DNA and host cell encoding residues 1-451 of SEQ ID NO:117, classified in Class 536, subclass 23.1. Claims 37-38 will be examined as they are drawn to the elected Group.

Group 31-41. Claim 57 is drawn to a method for the treatment of eleven different diseases, with a molecule of Group 1, starting with autoimmune diseases and ending with rejection after organ transplantation, respectively classified in Class 424, subclass 130.1. Applicant is required to a specific disease for examination.

Group 42-52. Claim 57 is drawn to a method for the prophylaxis of eleven different diseases, with a molecule of Group 1, starting with autoimmune diseases and ending with rejection after organ transplantation, respectively

classified in Class 424, subclass 130.1. Applicant is required to a specific disease for examination.

Group 53-63. Claim 57 is drawn to a method for the treatment of eleven different diseases, with a molecule of Group 2, starting with autoimmune diseases and ending with rejection after organ transplantation, respectively classified in Class 424, subclass 130.1. Applicant is required to a specific disease for examination.

Group 64-74. Claim 57 is drawn to a method for the prophylaxis of eleven different diseases, with a molecule of Group 2, starting with autoimmune diseases and ending with rejection after organ transplantation, respectively classified in Class 424, subclass 130.1. Applicant is required to a specific disease for examination.

Group 75. Claim 61 is drawn to a humanized anti-Fas antibody classified in Class 530, subclass 388+.

Group 76-79. Claim 62 is drawn to an antibody molecule comprising one or more heavy chains selected from the group consisting of SEQ ID NO:143, 145, 147 and 157, respectively. Applicant is required to elect a single heavy chain molecule or a specific combination of heavy chain molecules for examination. Claims 64, 66-81, 88-90, 103-104 will be examined as they are drawn to the elected Group.

Group 80-83. Claim 63 is drawn to an antibody molecule comprising one or more light chains selected from the group consisting of SEQ ID NO:107, 127, 129 and 113, respectively. Applicant is required to elect a single heavy chain molecule or a specific combination of light chain molecules for examination.

examination. Claims 65, 68-78, 81, 90, 105, 107 will be examined as they are drawn to the elected Group.

Group 84-87. Claims 82-85 are drawn to a method of treatment of a condition involving an abnormality in the Fas/Fas ligand system comprising administering an the antibody of claim 62, Classified in Class 424, subclass 130+. Applicant is required to elect a single heavy chain molecule or a specific combination of heavy chain molecules for examination.

Group 88-91. Claim 86 is drawn to a method of treatment of a condition involving an abnormality in the Fas/Fas ligand system comprising administering an the antibody that comprises one of more light chains selected from the group of SEQ ID NO. 127, 129, 131 and one or more heavy chains selected from the group of SEQ ID NO: 143, 145, 147, Classified in Class 424, subclass 130+. Applicant is required to elect a single heavy chain molecule or a specific combination of heavy chain molecules for examination and a single light chain molecule or a specific combination of light chain molecules for examination.

Group 92-95. Claims 91 is drawn to a DNA encoding an antibody molecule comprising one or more heavy chains selected from the group consisting of SEQ ID NO:143, 145, 147 and 157, respectively. Applicant is required to elect DNA encoding a single heavy chain molecule or a specific combination of heavy chain molecules for examination. Claims 92, 94-98 and 100-101 will be examined as they are drawn to the elected Group.

Group 16-99. Claims 93 is drawn to a DNA encoding an antibody molecule comprising one or more heavy chains selected from the group consisting of SEQ ID NO:143, 145, 147 and comprising one or more light chains selected from the group consisting of SEQ ID NO: 127, 129, 131, respectively. Applicant is required to elect DNA encoding a single heavy chain molecule or a specific combination of heavy chain molecules for examination and to elect DNA encoding a single light chain molecule or a specific combination of light chain molecules for examination. Claims 96, 99, 102 will be examined as they are drawn to the elected Group.

Group 100-106. Claim 106 is drawn to 7 different transformant strains each of which is a separate invention classified in Class 435, subclass 326. Applicant is required to elect a single invention.

Group 107-109. Claim 108 is drawn to a DNA encoding SEQ ID NO:127, 129, 131, respectively. Applicant is required to elect DNA for examination. Claims 109-116 and 118-119 will be examined as they are drawn to the elected Group. Applicant is required to identify the nucleotide sequence that is drawn to the elected Group.

Group 110-113. Claim 117 is drawn to a host cell transformed with a combination of DNA encoding SEQ ID NO:127, 129, 131, respectively. Applicant is required to elect a specific DNA combination for examination.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-3, 4-30, 75-83, 92-109 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 4, 31-74 and 84-91 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 2 and 4 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 1 and 31-74 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 76-79 and 84-87 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with

another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 80-83 and 88-91 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of all other products claimed and not at all related to the methods claimed because those products are not used in any of the methods claimed.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Groups 1 and 2 are further subject to election of a single disclosed species.

Claims 1, 6, 8 and 9 are generic to a plurality of disclosed patentably distinct species comprising light chain polypeptides of different structures and therefore different function wherein the light chains are (a) SEQ ID NO:50, (b) SEQ ID NO:54, © SEQ ID NO: 107 and SEQ ID NO:109, all of claim 26. Claims 28 and 29 will be examined as it is drawn to the elected light chain.

6. Groups 1 and 2 are further subject to election of a single disclosed species.

Claims 1, 6, 8 and 9 are generic to a plurality of disclosed patentably distinct species comprising heavy chain polypeptides of different structures and therefore different function wherein the heavy chains are (a) SEQ ID NO:89, (b) SEQ ID NO:117, all of claim 27. Claims 28-29 will be examined as it is drawn to the elected heavy chain.

7. Groups 1 and 2 are further subject to election of a single disclosed species.

Claims 1, 6, 8 and 9 are generic to a plurality of disclosed patentably distinct species comprising agents for the treatment or prophylaxis of dozens of conditions attributable to abnormalities of the Fas/Fas ligand system (claims 42-55). Applicant is required to elect a single condition and identify the claims that read on the elected species in the specifically elected group.

8. Groups 76-83 are further subject to election of a single disclosed species.

Claims 62, 67 and 68 are generic to a plurality of disclosed patentably distinct species comprising agents for the treatment or prophylaxis of dozens of conditions attributable to abnormalities of the Fas/Fas ligand system (claims 103-105). Applicant is required to elect a single condition and identify the claims that read on the elected species in the specifically elected group.

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
June 26, 2001

RESTRICTION ELECTION FACSIMILE TRANSMISSION

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